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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,501	08/09/2000	Susan Acton	MNI-132CP3	5106

7590 12/29/2003  
INTELLECTUAL PROPERTY GROUP  
MILLENNIUM PHARMACEUTICAL, INC.  
75 SIDNEY STREET  
CAMBRIDGE, MA 02139

EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/635,501		ACTON ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	B. Dell Chism		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-16, 44, 46 and 48-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-15 and 44 is/are allowed.
- 6) ☒ Claim(s) 16, 46 and 48-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This office action is in response to Applicants' response filed 09 October 2003. The Examiner acknowledges the Applicants' submission of Statement of Biological Culture Deposit ATCC Designation No. 209510.

The Examiner acknowledges the renumbering of the claims and bases all new comments on the renumbered claims.

The Examiner acknowledges Applicants' statement of not receiving the Page 2 of the previous office action upon attempts to get the missing page from the Examiner. The Examiner states for the record that the Page 2 was the statement of claims under consideration and the beginning of the Deposit Requirement to which the Applicants' obviated with submission of the Statement of Biological Culture Deposit ATCC Designation No. 209510.

### **Withdrawal of Objections and Rejections**

The rejections and/or objections made in the prior office action, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 09 October 2003 will be addressed to the extent that they pertain to the present grounds of rejection.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. (Withdrawn) Rejection of claim 5 is withdrawn due to Applicants' satisfaction of the Deposit Requirements set forth in the previous office action.

3. (New) Claim 16 (former claim 17) is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polypeptides of SEQ ID NOs: 4-5 that consist of at least 50 consecutive amino acid residues of SEQ ID NO: 2, does not reasonably provide enablement for any and/or all isolated polypeptides that could comprise at least 50 consecutive amino acid residues of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be

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considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

*The nature of the invention:* The claimed invention is drawn to isolated polypeptides comprising sequence similarity and similar bioactivities of SEQ ID NO: 2, which is an ACE-2 polypeptide.

*The state of the prior art and the predictability or lack thereof in the art:* The art is lacking in predictable teachings regarding the bioactivities of all possible isolated polypeptides of the claimed genus. The art does not teach the claimed ACE-2 bioactivities for all sequences possible derived from SEQ ID NO: 2, wherein the isolated polypeptide comprises at least 50 consecutive amino acid residues of SEQ ID NO: 2.

*The amount of direction or guidance present and the presence or absence of working examples:* Given the lack of teachings of predictability regarding the ACE-2 bioactivity of all possible isolated polypeptide derivatives of SEQ ID NO: 2 comprising at least 50 consecutive amino acid residues of SEQ ID NO: 2, detailed teachings are required to be present in the disclosure to enable the skilled artisan to make and use the isolated polypeptide derivatives comprising at least 50 consecutive amino acid residues of SEQ ID NO: 2 and that would

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maintain the required bioactivity as claimed. Such teachings are absent. The specification only discloses the sequences of SEQ ID NOs: 4-5. There is no disclosure of any other sequences comprising at least 50 consecutive amino acid residues of SEQ ID NO: 2 and that would maintain the required bioactivity as claimed.

*The breadth of the claims and the quantity of experimentation needed:* Given the lack of teachings of predictability found in the art regarding the bioactivity of any possible isolated polypeptide comprising at least 50 consecutive amino acid residues of SEQ ID NO: 2 and in the absence of sufficient disclosure in applicant's specification to overcome the lack of teachings of predictability in the art, it would require undue experimentation by one of skill in the art to be able to make and use the invention commensurate in scope with the claims.

4. (Maintained) Claim 46 (former claim 47) was rejected for lacking written description wherein the claim was drawn to a genus, i.e., "isolated polypeptides comprising amino acid sequences which are at least 90% identical to the amino acid sequence set forth in SEQ ID NO: 2, wherein said polypeptide has at least one bioactivity..." This rejection was not addressed in Applicants' response and the rejection was not obviated by amendment in the response, thus, the rejection is maintained for lacking written description for the claimed genus.

5. (Withdrawn) Claim 16 (former claim 17) was rejected for lack of written description for "biological activities", however, Applicants amendments obviated the rejection by defining the biological activities of ACE-2 that the claims are drawn.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. (Withdrawn) The rejection of claims 8-9, 16 and 46 (former claims 17 and 47) for indefinite language has been withdrawn in light of Applicants' amendments.
8. (Withdrawn) The rejection of claims 3-4 and 10-16 for depending from rejected claims is withdrawn since rejection of the claim is withdrawn.
9. (Maintained) The rejection of claims 48-57 (formerly claims 49-58) is maintained, as these claims are dependent on rejected claims 16 and 46 (formerly claims 17 and 47).

***Conclusion***

Claims 3-15 and 44 are free of the art. Claims 16, 46 and 48-57 are rejected.

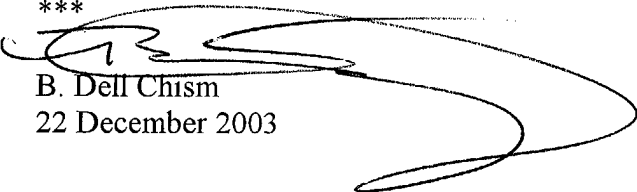
Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism  
22 December 2003



CHRISTOPHER R. TATE  
PRIMARY EXAMINER